**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456<br>Civil Action No. 01-12257-PBS |
| | Hon. Patti B. Saris |
| THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339 | |

**THE JOHNSON & JOHNSON DEFENDANTS'**
**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION**
**FOR PARTIAL SUMMARY JUDGMENT AGAINST ALL TRACK 1 DEFENDANTS**

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## Other Authorities

Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, L.P. (the "J&J Defendants") respectfully submit this Memorandum in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against all Track 1 Defendants.

**PRELIMINARY STATEMENT**

After five years of litigation, plaintiffs' case against the J&J Defendants has collapsed. After demanding and receiving a mountain of discovery, plaintiffs have discovered a simple, unassailable truth: the J&J Defendants' AWPs were not "inflated," and no class member was ever deceived.

According to plaintiffs, this case is about companies that "gamed the system" with prescription drugs with so-called "mega-spreads." As the J&J Defendants' summary judgment motion makes abundantly clear, the pricing of the J&J Defendants' two physician-administered drugs, Procrit and Remicade, bear no resemblance to these characterizations, because they were subject to limited (Procrit) or no discounting (Remicade). When their spreads are calculated correctly, using plaintiffs' own methodology, they do not exceed plaintiffs' 30% yardstick for spreads allegedly tainted by "the AWP scheme." Thus, as described below, plaintiffs' rhetoric about "manipulation" and "marketing" of spreads has no application to the J&J Defendants.

The J&J Defendants have been saying from the outset that they do not belong in this case. Plaintiffs' motion for partial summary judgment must be denied, and the J&J Defendants' motion for summary judgment should be granted.

## ARGUMENT

### I. PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT MUST BE DENIED BECAUSE IT IS BASED ON ALLEGATIONS THAT ARE LEGALLY IRRELEVANT, GENUINELY DISPUTED, OR FALSE

#### A. The Summary Judgment Standard

The standard for summary judgment is discussed in the Track 1 Defendants' Joint Memorandum, and will not be repeated here. Plaintiffs do not come close to satisfying their heavy burden of proving that they are entitled to judgment as a matter of law. *See* Track 1 Defendants' Joint Memorandum in Opposition to Plaintiffs' Motion for Partial Summary Judgment ("Track 1 Joint Memo."), Point I.

#### B. The Fact that AWP Was Used as a Reimbursement Benchmark Is Neither Disputed Nor Relevant to Plaintiffs' Liability Claim

Plaintiffs devote seven pages to proving the unremarkable proposition that AWP was used as a reimbursement benchmark during the class period, and that each Track 1 defendant "agrees" that AWP was used as a reimbursement benchmark. Pl. Memo. at 3-10.

Of course AWP was used as a reimbursement benchmark, and of course the J&J Defendants "agree" that it was used as a reimbursement benchmark. AWP was used as a reimbursement benchmark *before* the class period, it was used as a reimbursement benchmark *during* the class period, and most payors are continuing to use it as a reimbursement benchmark five years *after* these lawsuits were filed. In fact, Blue Cross Blue Shield of Massachusetts, a named representative for Class 3, recently testified that, after a thorough review of its options, it decided to begin using AWP as the basis for reimbursing drugs administered in hospitals. It expects that the move to AWP-based reimbursement will enable it to achieve substantial savings. *See* Deposition of Sheila R. Cizauskas at 125-26, 140 (March 10, 2006) (Declaration of Andrew D. Schau ("Schau Decl.") submitted herewith, Exh. 1).

### C. The Fact that the J&J Defendants Submitted AWPs for Procrit and Remicade to Wholesalers and Independent Publishers Is Neither Disputed Nor Relevant to Plaintiffs' Liability Claim

Defendants devote six pages of their brief to proving that the J&J Defendants "caused" AWPs to be published. Pl. Memo. at 34-40. The J&J Defendants do not dispute that they submitted AWPs, or in some cases, "recommended" AWPs, to wholesalers and independent publishing services, and that the AWPs they submitted for Procrit and Remicade were 120% and 130% of their respective list prices. *See* The J&J Defendants' L.R. 56.1 Counter-Statement of Disputed Material Facts in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants ("J&J Counter-Statement"), Counter-Statement No. 3. The submission of AWPs and list prices to wholesalers and publishers has been standard practice in the pharmaceutical industry for decades. *See* Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris (Feb. 9, 2005), ¶¶ 20-31 (Schau Decl., Exh. 2).

### D. The AWPs for Procrit and Remicade Were Not Unlawful and They Did Not Violate OIG's 2003 Voluntary Guidance Document

As set forth in the J&J Defendants' motion for summary judgment, plaintiffs' expert, Dr. Hartman, asserts that AWP has two meanings, depending on the identity of the payor. He says it should equal ASP under Medicare (his "zero by statute" theory), and must be within 30% of ASP for private payors (his "expectation" theory). *See* J&J Summary Judgment Memo. at 2. In their latest motion, however, plaintiffs cannot decide what AWP is supposed to be. On the one hand, they assert that AWP is supposed to "reflect actual costs in the marketplace," and thus should include unspecified but "relevant" discounts. Pl. Memo. at 42, 46. On the other hand, they argue that AWP need not reflect actual market prices but need only be "***reasonably related***" to market prices *Id.* at 42 (original emphasis). Elsewhere plaintiffs concede that AWP is simply a "benchmark." *Id.* at 3, 4.

As the Court is well-aware, AWP is not defined in any statute or regulation. *See* H.R. Rep. 107-801, at 94 (Jan. 2, 2003) ("AWPs, however, are not defined by law or regulation."). Although plaintiffs pay lip service to the idea that AWP has a "plain meaning" that is susceptible to a "simple construction," the only definition they offer is convoluted and unworkable. AWP, according to plaintiffs, is supposed to be "a mean, proportion or medial, or a typical or usual, amount that intermediaries pay before resale to the ultimate consumers." Pl. Memo. at 43.

This definition of AWP makes no sense. The "mean" price of a drug may not be its "typical" or "usual" price, so a manufacturer seeking to apply plaintiffs' definition of AWP would be at a loss to know what to report.[1] The issue is further confused by plaintiffs' suggestion that AWP should be a "proportion" [sic?] amount, a term that has no discernable meaning whatsoever.

Lacking a coherent and legally binding definition of AWP, plaintiffs quote language in an OIG voluntary guidance document stating that manufacturers should "accurately take into account price reductions." Pl. Memo. at 44. However, as set forth in the Track 1 Defendants' Joint Memorandum, that language has nothing to do with AWP, but refers instead to other types of reported prices, such as "Best Price" and "AMP," which are defined by statute, and which do require manufacturers to include specified price incentives. *See* Track 1 Joint Memo., Point III.C.

[1] For example, if 10 units of a drug are sold for $10 per unit, and five units are sold for $8 per unit, the "mean" price is $9.33 per unit, even though that amount is not "typical" or "usual."

### E. The J&J Defendants Did Not "Manipulate" and "Market" the Spread on Procrit and Remicade

The meat of plaintiffs' submission is that each of the Track 1 defendants allegedly "manipulated" and "marketed" the spreads on their drugs, and that this conduct should be considered unfair and deceptive under Massachusetts law.[2] Plaintiffs draw an analogy to conduct the OIG thinks may be unlawful under the federal anti-kickback statute. Pl. Memo. at 44-45. In particular, the OIG has taken the position that "The *conjunction* of *manipulation* of the AWP to induce customers to purchase a product with the *active marketing* of the spread is strong *evidence* of the unlawful *intent* necessary to trigger the anti-kickback statute." OIG Compliance Program For Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003) (emphasis added).

The OIG's interpretation of the federal anti-kickback statute is not controlling under Massachusetts Gen. Laws Ch. 93A. In fact, the OIG's guidance document is not even controlling under federal law. *See* Track 1 Joint Memo., Point III.C.1. But even if the Court were to consider the OIG's guidelines, they offer no support for plaintiffs' claims against the J&J Defendants, because the spreads on Procrit and Remicade are minimal.

Like the term "AWP," the terms "manipulation" and "active marketing" are not defined. Judge Woodlock aptly described the application of AWP to the anti-kickback statute as a "yeasty area," and he questioned whether the anti-kickback law could ever be violated in a legal environment as "open-textured" as this. *United States v. Mackenzie*, CR-01-10350-DPW (D. Mass.), Tr., Day 39 at 6 (June 24, 2004) (Track 1 Joint Memo., Exh. A). Nevertheless, it is at least clear that the OIG does not think the federal anti-kickback statute is implicated unless

[2] The claims of the Class 1 representatives for Procrit and Remicade are governed by the laws of Nevada and Oklahoma, not Massachusetts. *See* J&J Summary Judgment Memo. at 13-14 and 21-23. Plaintiffs do not argue that they are entitled to summary judgment under the laws of these states.

there is both "manipulation" of AWP and "active marketing" of the spread. Neither "manipulation" nor "active marketing" alone is sufficient evidence of unlawful intent, and the mere existence of a "spread" between list price and AWP is not actionable. *Id.* (July 24, 2004) (Charge Conference, Tr. at 67-68) ("everybody got the spread between AWP and list price, the same 25 percent…. That's there. That's what Congress expected with AWP.") (Statement of Asst. U.S. Attorney Michael K. Loucks) (Schau Decl., Exh. 3).

**1. The J&J Defendants Did Not "Manipulate" the AWPs for Procrit and Remicade**

**a. Procrit**

Ortho Biotech did not "manipulate" Procrit's AWP, and plaintiffs make no credible argument that it did. In fact, the evidence affirmatively shows that Ortho Biotech did not manipulate Procrit's AWP.

By plaintiffs' own admission, the spreads on Procrit rarely exceeded Dr. Hartman's so-called "speed limit" of 30%. In Dr. Hartman's initial report, he concluded that, between 1991 and 2003, only 16 out of 116 Procrit NDCs exceeded 30%, and 8 of these 16 spreads were between 30% and 33%. *See* J&J Summary Judgment Memo. at 4-5, 8. Although Dr. Hartman initially asserted that three Procrit NDCs exceeded 50%, he withdrew that assertion when he filed his Supplemental Report. *Id.* at 8, n.9. As illustrated in the following chart, when other errors in Dr. Hartman's calculations are corrected, only one of Procrit's spreads out of 116 exceeds 30%, and even that isolated figure may reflect anomalies in the data, rather than genuine price reductions. *Id.* at 10.[3]

[3] At his deposition, Dr. Hartman struggled to defend his assertion that Procrit's modest spreads were improper. He admitted that Ortho Biotech's pricing did not represent an "exaggerated exploitation" of the reimbursement system because Procrit's spreads only "nudged against the speed limit." He even said he thought the resulting damages would not be "a whole heck of a lot." Deposition of Raymond S. Hartman

**Procrit Spreads > 30% (Corrected)**

| Procrit NDC | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 00062740003 | | | | | | | | | | | | | |
| 00062740103 | | | | | | | | | | | | | |
| 00062740201 | | | | | | | | | | | | | |
| 00062740501 | | | | | | | | | | | | | |
| 59676030201 | | | | | | | | | | | | | |
| 59676030202 | | | | | | | | | | | | | |
| 59676030301 | | | | | | | | | | | | | |
| 59676030302 | | | | | | | | | | | | | |
| 59676030401 | | | X | | | | | | | | | | |
| 59676030402 | | | | | | | | | | | | | |
| 59676031001 | | | | | | | | | | | | | |
| 59676031002 | | | | | | | | | | | | | |
| 59676031201 | | | | | | | | | | | | | |
| 59676032001 | | | | | | | | | | | | | |
| 59676034001 | | | | | | | | | | | | | |

Plaintiffs simply ignore the calculations showing that Procrit's spreads were minimal. Instead, plaintiffs argue that Procrit's AWP was "manipulated" because Ortho Biotech (1) never sold Procrit at AWP or for more than the list price, and (2) "never *adjusted* its AWPs" to reflect discounts and rebates. Pl. Memo. at 104-106 (emphasis added).

Plaintiffs' theory of what constitutes "manipulation" of AWP is completely unsupported. A company is not required sell a product for more than the list price, and it is not prohibited from offering discounts and rebates. Both practices are routine, and both are completely lawful. *See* Deposition of Meredith Rosenthal, Ph.D. at 212-13 (Feb. 22, 2006) and 322-23 (Feb. 23, 2006) ("Rosenthal Dep.") (Schau Decl., Exh. 4). Furthermore, plaintiffs cite no law – and there is no law – that would require a company to "adjust" its AWPs to reflect discounts and rebates. Failing to do something that one is not obligated to do cannot be a "manipulation" of anything.

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("Hartman Dep.") at 1232 (Mar. 1, 2006) (Schau Decl., Exhibit 5). Nevertheless, he found liability because, according to his *per se* liability rule, "the speed limit is what it is." *Id.* at 1235.

If, as plaintiffs contend, pharmaceutical manufacturers were legally obligated to adjust their AWPs every time they gave a customer a discount or rebate, liability would be nearly universal. Nearly all pharmaceutical products are discounted to one degree or another (Remicade is an exception), yet there is no evidence that any pharmaceutical company has ever "adjusted" its AWPs. Indeed, it appears that no one besides plaintiffs' counsel has even thought about "adjusting" AWP.[4] Any attempt to impose liability in this circumstance would contravene Massachusetts law. *Cf. Govoni & Sons Constr. Co. v. Mechanics Bank*, 51 Mass. App. Ct. 35, 51, 742 N.E.2d 1094, 1107 (Mass. App. Ct. 2001) (practices that are "widely utilized" in an industry do not qualify as unfair conduct under Chapter 93A).

Moreover, as applied to Procrit, plaintiffs' proffered definition of "manipulation" is facially absurd. Plaintiffs ask the Court to rule – as a matter of Massachusetts law – that a 29% spread is lawful because the AWP was not "manipulated," whereas a 31% spread is unlawful because the AWP was "manipulated." This is no mere *reductio ad absurdum*. It is exactly what plaintiffs are claiming. For example, according to Dr. Hartman, the spread in 1995 on the 2000 unit vial of Procrit (NDC 59676030202) was 29.6%, whereas the spread on the 10,000 unit vial (NDC 59676031001) was 30.3%. Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages (Dec. 15, 2005),

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[4] If a company had tried to "adjust" its AWPs, as plaintiffs suggest was required, it would have encountered intractable difficulties determining how the adjusted AWP should be calculated. Is AWP supposed to be adjusted daily, weekly, monthly, quarterly, annually? Should the adjustment take account of hospital discounts, government discounts, and discounts given to class members, or should these discounts be excluded? How does one account for volume-based rebates where the ultimate selling price remains indeterminate until the end of the contract period when the volume of sales becomes known? Should the adjusted AWPs be calculated on a per-unit basis for all NDCs in a product line, or should they be calculated separately for each NDC? Can a manufacturer change the way it calculates or reports its adjusted AWPs if its competitor calculates and reports its adjusted AWPs differently? If the adjusted AWPs must "reasonably relate" to market prices, what relation to market price is "reasonable"? What relationship to market price is "unreasonable"? Is the adjusted AWP for private payors the same as the adjusted AWP for Medicaid? Is it the same as the AWP for Medicare? What if they pay different prices? How many different adjusted AWPs is the manufacturer supposed to publish?

Attachment G.4.c. Although the difference between these two spreads is a scant 0.7%, Dr. Hartman finds liability in the one case but not in the other. *Id.*, Attachment I.4.

More generally, plaintiffs' proffered definition of "manipulation" defies common sense. Under plaintiffs' theory, there can be no "manipulation" of AWP if there are no discounts and rebates. But plaintiffs' own experts agree that discounting is a legitimate and lawful response to competition. *See* Rosenthal Dep. at 212-13, 322-23; Hartman Dep. at 1193, 1232. Plaintiffs' proposed rule would discourage companies from competing based on price, a result that is nothing short of perverse. *Cf. Tagliente v. Himmer*, 949 F.2d 1, 7 (1st Cir. 1991) (price competition alone does not violate Chapter 93A).

In short, plaintiffs' claim that Procrit's AWP was "manipulated" is contradicted by the facts and unsupported by any applicable law.

**b. Remicade**

Plaintiffs do not even attempt to argue that Centocor "manipulated" Remicade's AWP. In fact, it is perfectly clear that Remicade's AWP was not manipulated. The *published* difference between Remicade's list price and AWP is 30%. Because Centocor did not offer discounts and rebates, the difference between Remicade's market price and AWP was also 30%. *See* J&J Summary Judgment Memo. at 16-18. According to plaintiffs, payors know about, and pay attention to, the published differences between AWP and list price, and they interpret these figures as "signals" that inform their "expectations as to transactions prices." Hartman Dep. at 1181, *see also id.* at 678, 682, 683-85 (Feb. 27, 2006). If plaintiffs are correct, then the "signals" sent by Remicade's published list price and AWP are accurate. *See* J&J Summary Judgment Memo. at 15-16. If anything, because payors understand and expect that drugs frequently can be acquired for less than the published list price, the signals conveyed by Remicade's published list price and AWP would lead payors to assume that Remicade's acquisition price was even lower

than it actually was. Hartman Dep. at 682-85. This would suggest that payors mistakenly paid too little for Remicade, rather than too much.

**2. The J&J Defendants Did Not "Market" the Spreads on Procrit and Remicade**

**a. Procrit**

Plaintiffs assert that Ortho Biotech "marketed" Procrit's spread. The evidence they cite proves nothing of the sort. In fact, it proves the opposite.

To be clear, it is not wrong or unlawful to provide doctors with truthful information about a drug's cost and reimbursement. Nevertheless, because Procrit's spread was minimal, and because the reimbursement on Amgen's competing product, Aranesp, was more favorable, discussing the spread on Procrit was generally not in Ortho Biotech's interest. *See* J&J Counter-Statement No. 67. In fact, the relative spread on Procrit was so modest that U.S. Oncology, the largest network of cancer care physicians in the United States, actually discouraged its physicians from administering the drug. Declaration of Thomas C. Hiriak in Support of the Johnson & Johnson Defendants' Motion for Summary Judgment as to Class 1 and Class 2 ("Hiriak Decl."), ¶ 56 and Exh. 6.

Plaintiffs cite no evidence in their motion that Ortho Biotech marketed the spread. In fact, most of the evidence they reference concerns Ortho Biotech's knowledge that physicians were usually reimbursed at more than their acquisition cost, and that some physicians, particularly oncologists, understood that administering "supportive care drugs such as Procrit" was "economically attractive." Pl. Memo. at 107. Evidence that Ortho Biotech was aware that physician reimbursement generally exceeded acquisition cost is not actionable under any theory. In fact, Congress intended Part B reimbursement to exceed acquisition cost. *See* Memorandum of Law in Support of Track 1 Defendants' Joint Motion for Summary Judgment at 7-8.

Plaintiffs also allege that Ortho Biotech provided its sales force with "sales materials" that "highlighted the financial benefit of the spread to customers." Pl. Memo. at 108. This allegation is false. In fact, it is proven false by the very evidence plaintiffs cite:

- JJ Ex. 22. This document compares the amount of money a physician could earn by administering Procrit instead of sending the patient for a blood transfusion. *This is not an Ortho Biotech document and Ortho Biotech did not give the document to its sales force*. The sales representative whose file it came from thinks she may have received it from another sales representative, but she does not think she ever used it. Because it was not an approved Ortho Biotech sales piece, its use would have violated Ortho Biotech's policy. *See* Declaration of Patricia Hawley in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against The Johnson & Johnson Defendants, ¶¶ 3-5.

- JJ Ex. 23. This is an internal Ortho Biotech document that shows that Procrit *costs less* than Aranesp. The document points out that, because Procrit is less expensive, a patient receiving Procrit will incur a lower "patient co-pay." In particular, a patient receiving Procrit for 18 weeks will save $1,200 relative to the cost of Aranesp. The document does not mention physician reimbursement or profit.

- JJ Ex. 24. This is another internal Ortho Biotech document. Contrary to plaintiffs' representation, the document does not show that physicians could earn "$8,000 in AWP reimbursement" per patient. Pl. Memo. at 108. Rather, the $8,000 amount is a reference to the physician's *cost* of acquiring a 16-week regimen of Procrit. The document has nothing to do with reimbursement or profit. *See* Declaration of Scott Shelhamer in Opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants, ¶ 4.

- JJ Ex. 25. Plaintiffs represent that physicians were shown "certain CDs" that "refer to AWP." Pl. Memo. at 109. Plaintiffs' representation is false. The only Ortho Biotech CD that referred to AWP was a CD that was shown to *payors*, not physicians. The CD was used to demonstrate that the "cost of therapy" was lower for Procrit than for Aranesp, *i.e.*, that payors (and patients) would save money if physicians could be persuaded to administer Procrit instead of Aranesp. *See* Deposition of Thomas Hiriak at 445-49 (Nov. 10, 2004) (Schau Decl., Exh. 6).

There is nothing wrong with telling a physician how much a drug costs and how much the physician can expect to receive in reimbursement. Nevertheless, the evidence that plaintiffs cite as proof that Ortho Biotech marketed Procrit's spread actually proves that Ortho Biotech did not market Procrit's spread. To the contrary, the record shows that Ortho Biotech

marketed the fact that Procrit was *less expensive* than Aranesp, resulting in cost savings for payors, physicians, and patients.

**b. Remicade**

Centocor does not dispute that it provided physicians with information about the cost of Remicade and the expected level of reimbursement. *See* J&J Counter-Statement No. 67. As noted above, because physicians did not receive discounts and rebates, the information that Centocor discussed with physicians was known to payors, and was a matter of public record.

Centocor's discussion of the costs and benefits of in-office infusion was appropriate for the reasons set forth in the declaration of John Hoffman that was submitted in support of the J&J Defendants' Motion for Summary Judgment as to Class 1 and Class 2. *See also* J&J Counter-Statement No. 67. Specifically, the physicians to whom Remicade was marketed were not familiar with physician-administered drugs, were reluctant to incur the expense and risk of administering Remicade in their offices, and would otherwise have sent their infusion patients to the hospital where the cost of reimbursement was higher. *Id.*

Some of the materials relating to Centocor's Practice Management Program, including Centocor's Office-Based Infusion Guide, are attached to plaintiffs' papers as JJ 33, JJ 34, and JJ 36. These documents show that Centocor promoted in-office infusion based on the fact that the physician's office is the best and most cost effective site of care. *See* JJ 33 at MDL-CEN00003481 (listing the benefits of in-office infusion).

Plaintiffs sharply criticize Centocor because the Office-Based Infusion Guide included a one-page "Financial Impact Worksheet" designed to enable the physician to determine, based on the particular circumstances of his or her practice, including "payer mix, payer policies, office costs and more," whether in-office infusion would yield "income or loss" to the physician's individual practice. *Id.* at MDL-CEN00003485. Although plaintiffs do not

contend that the cost and reimbursement information Centocor provided to physicians was inaccurate, they maintain that providing such information is illegal in Massachusetts because it constitutes "marketing the spread." *See* Pl. Memo. at 121 (marketing the spread "falls within the penumbra of common-law, statutory, or other established concept of unfairness").

Centocor's efforts to educate physicians and payors about the benefits of in-office infusion resulted in improved patient care and reduced reimbursement costs. *See* J&J Counter-Statement No. 67. It is not improper – let alone illegal – for a manufacturer to provide physicians with truthful information about the cost of a drug and the expected level of reimbursement. There is no evidence – nor could there be – that furnishing this type of information to physicians caused class members to pay more for Remicade than they would have paid if this information had been withheld. This is particularly true for Remicade, where the absence of discounts and rebates means that the "spread" between the physician's acquisition cost and the published AWP is completely transparent.[5]

### F. The J&J Defendants' Conduct Was Not Deceptive or Unfair Under Mass. Gen. Laws Ch. 93A

Ortho Biotech and Centocor did nothing wrong, and their marketing of Procrit and Remicade was not deceptive or unfair. As set forth above, the spreads on these drugs, which were nearly always 30% or less, are entirely lawful, even under plaintiffs' liability theory. If, as plaintiffs admit, such spreads are "untainted by the AWP scheme," they cannot possibly be actionable under Chapter 93A.

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[5] Moreover, any interpretation of Chapter 93A that would make it illegal to engage in *truthful* discussions relating to cost and reimbursement would conflict with the First Amendment's protection of commercial speech. *See El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F. 3d 110, 113 (1st Cir. 2005) (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980)).

Certainly, the J&J Defendants did nothing "immoral, unethical, oppressive or unscrupulous." *PMP Assocs., Inc. v. Globe Newspaper Co.*, 366 Mass. 593, 596, 321 N.E.2d 915 (1975) (citing *FTC v. Sperry & Hutchison Co.*, 405 U.S. 233, 244 (1972)). Nor does their conduct rise to the "level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce," or leave a "rancid flavor of unfairness." *Levings v. Forbes & Wallace, Inc.*, 8 Mass. App. Ct. 498, 504, 396 N.E.2d 149 (Mass. App. Ct. 1979); *Mass. Employers Ins. Exch. v. Propac-Mass, Inc.*, 410 Mass. 39, 43, 648 N.E.2d 435 (1995). There is no evidence that their conduct resulted in "substantial injury to consumers, competitors or other business people." *PMP Assocs., Inc.*, 336 Mass. at 596, 321 N.E.2d at 918.

Essentially, plaintiffs' case against the J&J Defendants boils down to using pejorative rhetoric to describe lawful conduct. Plaintiffs thus characterize Ortho Biotech's failure to "adjust" Procrit's AWP as improper "manipulation," even though Ortho Biotech had no duty to adjust AWP, and there is no evidence that any pharmaceutical company has *ever* adjusted its AWPs. Similarly, plaintiffs characterize Centocor's truthful and open discussions about Remicade's cost and reimbursement as "marketing the spread," even though the physicians to whom Remicade was marketed were not familiar with in-office infusion and had a legitimate interest in knowing whether providing infusion services was economically viable, *i.e.*, would result in "income or loss" to the physician's practice. Pl. Ex. JJ 33 at MDL-CEN00003485. In other words, plaintiffs' heated rhetoric does not fit the facts. To quote Gertrude Stein, "There is no there there."

Procrit and Remicade were appropriately priced and marketed. There is not a shred of evidence that class members were deceived. The J&J Defendants did not violate Massachusetts law.

## CONCLUSION

The J&J Defendants respectfully request that plaintiffs' motion for partial summary judgment be DENIED.

Dated: April 7, 2006

/s/ William F. Cavanaugh, Jr.

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Adeel A. Mangi
Mark G. Young
Niraj Parekh
**PATTERSON BELKNAP WEBB & TYLER LLP**
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000